UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IN RE: ZIMMER NEXGEN KNEE IMPLANT PRODUCTS LIABILITY LITIGATION	)	**MDL No. 2272**
	)	**Master Docket No. 11 C 5468**
This Document Relates to All Cases	)	
	)	**Hon. Rebecca R. Pallmeyer**

MEMORANDUM OPINION AND ORDER

Plaintiffs, more than 500 individuals who underwent total knee replacement ("TKR") surgeries, bring suit against Defendants, Zimmer Inc. and its affiliates (collectively, "Defendants" or "Zimmer"), manufacturers of the Zimmer NexGen Knee system. Plaintiffs allege that certain components of that system are prone to premature loosening, which has led to pain and loss of movement, necessitating revision surgery in some cases. On August 8, 2011, the United States Judicial Panel on Multidistrict Litigation issued a transfer order consolidating Plaintiffs' cases in this court for pretrial proceedings**.**

Pursuant to this court's Order of December 19, 2011, Plaintiffs filed a Master Long Form Complaint and Jury Demand (the "Master Complaint") on January 12, 2012. Defendants filed a motion to dismiss, in part, the Master Complaint on March 14, 2012. For the reasons explained below, Defendants' motion is denied.

BACKGROUND[1]

[1] Though the court primarily draws Plaintiffs' factual allegations from the Master Complaint, the court is not confined to the four corners of the complaint. *See Geinosky v. City of Chicago*, 675 F.3d 743, 745 n.1 (7th Cir. 2012) ("[A] party opposing a Rule 12(b)(6) motion may submit materials outside the pleadings to illustrate the facts the party expects to be able to prove."). The court also considers factual allegations consistent with the pleadings presented in Plaintiffs' Technical Memorandum on Knee Anatomy, Total Knee Replacement and the Zimmer NexGen High-Flexion Components and MIS Surgical Technique [210] (hereinafter "Pls.' Technical Mem."), Plaintiffs' scientific presentation to the court on January 12, 2012, and Plaintiffs' Memorandum in Opposition to Defendants Zimmer Entities' Motion to Dismiss, In Part, Master Long Form Complaint and Jury Demand [428] (hereinafter "Pls.' Resp.").

Plaintiffs' claims involve a tibial component designed for use with minimally invasive surgery techniques (the "MIS Tibial component"), and four "high-flex" femoral components (the Cruciate Retaining (CR) Flex and Legacy Posterior Stabilized (LPS) Flex components, and the "Gender Solutions" versions thereof (collectively, the "Flex femoral components")). (Master Long Form Compl. & Jury Demand [211] (hereinafter, "Master Compl."), ¶ 7.)[2] According to Plaintiffs, the MIS Tibial component, approved by the FDA in 2005, was a "low profile design" intended to be implanted using a smaller incision, with the benefits of reduced blood loss, less pain, shorter hospital stays, and shorter rehabilitation. (*Id.* ¶¶ 64, 88.) In 2010, after a study found a significantly higher failure rate among MIS Tibial components when implanted without a drop-down stem that extended further into the tibia (*id.* ¶ 149), and after Zimmer had received complaints of loosening of the implanted devices requiring revision surgery (*id.* ¶ 155), Zimmer issued an "Urgent Field Safety Notice"/ "Urgent Device Correction" letter to all customers using the MIS Tibial component (*id.* ¶ 115). The letter cautioned that the "MIS procedures are inherently challenging and can involve reduced visibility, which may lead to difficulty with achieving proper implant alignment and cement fixation" (*id.* ¶ 115), and further warned against implanting the device without the drop-down stem (Pls.' Technical Mem. at 13). In September of 2010, the FDA classified Zimmer's response as a Class II recall of more than 68,000 MIS Tibial components, noting that the FDA had received 114 Medical Device Reports of loosening that required revision surgery. (*Id.* ¶¶ 17, 155-56.)

Though the Flex femoral components have not been similarly subject to a recall, Plaintiffs allege that these components are similarly prone to loosening. The Flex femoral components are "high-flex" devices, designed to accommodate flexion (bending of the knee), up to 155 degrees.

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[2] The difference between CR-Flex and LPS-Flex knee designs is whether the patient's posterior cruciate ligament is retained. In LPS-Flex knees, the cruciate ligament is sacrificed and replaced with a tibial post and femoral notch that perform the function of the posterior cruciate ligament. (*Id.* ¶¶ 55-56.) The Gender Solutions versions of these two products are femoral components designed specifically for women. (*Id.* ¶ 65.)

(*Id.* ¶¶ 9, 62-63; Pls.' Technical Mem. at 7-8.) While a typical, healthy knee has the capacity to bend between 155 to 160 degrees, the Zimmer NexGen non-Flex knees that preceded the Flex versions were able to achieve only between 120 to 130 degrees of flexion. (Master Compl. ¶¶ 9, 39, 57.) Plaintiffs allege that Zimmer marketed the Flex knee design for patients with more active lifestyles, particularly for those who garden or kneel for prayer, or for those whose cultural activities and lifestyles require considerable squatting or kneeling activities. (*Id.* ¶¶ 102-10.)

Plaintiffs cite to a number of studies in peer-reviewed journals, however, that observe high rates of loosening for Flex femoral components. (Master Compl. ¶ 128-29; Pls.' Technical Mem. at 11; Pls.' Resp. at 31.)[3] The studies hypothesize that the loosening is caused by asymmetric distribution of the heightened forces during deep knee flexion. *See* P. Bollars et al., *Femoral Component Loosening in High-Flexion Total Knee Replacement*, 93-B J. Bone & Joint Surgery 1355, 1361 (2011) ("[H]igh-flexion designs have a greater risk for loosening of the femoral component than conventional TKR designs. The absence of femoral load sharing between the prosthetic component and the condylar bone during flexion is in our opinion an important contributing factor."); Sung-Do Cho et al., *Three- to Six-Year Follow-Up Results After High-Flexion Total Knee Arthroplasty: Can We Allow Passive Deep Knee Bending?*, 19 Knee Surgery, Sports Traumatology, Arthroscopy 899, 903 (2011) ("[W]ith passive deep knee bending, excessive compressive force could be applied at the posterior femoral condyle, leading to distal shear and anterior tensile forces . . . . Inadequate bony support of the posterior femoral condyle may result in micromotion and early loosening of the femoral component."); H. S. Han et al., *High Incidence*

[3] Plaintiff also cites to a study conducted by Drs. Robert Berger and Craig Della Valle, presented at the American Association of Orthopaedic Surgeons in March 2010, in which the authors observed that out of 108 CR-Flex femoral components examined, 39 showed signs of loosening, 9 were revised for failed femoral loosening, and 1 was subject to an impending revision. (Master Compl. ¶¶ 140-41.) Dr. Berger, who was involved in the design of the NexGen Flex Knee system, was later the subject of a *New York Times* article reporting on his findings. (*Id.* ¶¶ 13, 136-37.).

of Loosening of the Femoral Component in Legacy Posterior Stabilised-Flex Total Knee Replacement, 89-B J. Bone & Joint Surgery 1457, 1460 (2007) ("If deep knee flexion is achieved, asymmetrical loading between the medial and lateral compartments of a TKR may contribute to loosening and failure of the implant.").[4] Plaintiffs also question whether NexGen Flex femoral components offer any real benefit in flexion, citing studies that show no statistically significant difference in the range of motion achieved by those with Flex devices when compared with that of those implanted with their non-Flex counterparts. (Master Compl. ¶¶ 127, 131.)

DISCUSSION

I. Applicability of Rule 12(b)(6)

As a preliminary matter, the parties disagree about whether Defendants are entitled to bring a motion to dismiss particular causes of action in Plaintiffs' Master Complaint. Plaintiffs raise two objections to 12(b)(6) motion practice: (1) that Defendants waived their right to bring a motion to dismiss when, prior to the consolidation of these cases in this Multidistrict Litigation ("MDL"), the Defendants filed answers to the complaints in individual actions involving each of the devices at issue;[5] and (2) that the Plaintiffs' individual actions should not be subject to a "master motion to

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[4] The studies admit that other factors such as physician error and patient lifestyle may also contribute to loosening, and note the limitations of their methodologies. Bollar et al., *supra*, at 1361 (noting that *in vitro* laboratory testing could not replicate conditions *in vivo*, such as a patient's lifestyle); Cho et al., *supra*, at 903 (noting limitations in a retrospective analysis of the authors' own patients, including a lack of control group); Han et al., *supra*, at 1460 (noting the weakness in the "retrospective, non-comparative design and the relatively small number of patients").

[5] Cases in which Defendants filed answers prior to consolidation in this MDL include: *Teague v. Zimmer, Inc.*, No. 11 C 5727 (LPS Flex); *Singsaas v. Zimmer, Inc.*, No. 11 C 5474 (LPS Flex and MIS tibial component); *Davis v. Zimmer, Inc.*, No. 11 C 5472 (LPS Flex); *Barlow v. Zimmer, Inc.*, No. 11 C 5758 (LPS Flex); *Sizemore v. Zimmer, Inc.*, No. 11 C 5477 (CR Flex); *Sloan Perry v. Zimmer, Inc.*, No 11 C 5725; *Mees v. Zimmer, Inc.*, No. 11 C 5724 (CR Flex); *Hayes v. Zimmer, Inc.*, No. 11 C 5716 (CR Flex); *Genslinger v. Zimmer, Inc.*, No. 11 C 5726 (CR Flex); *Cleveland v. Zimmer, Inc.*, No. 11 C 1210 (CR Flex and MIS tibial component); *Wahlman v. Zimmer, Inc.*, No. 11 C 5486 (Gender Solutions CR Flex); *Anderson v. Zimmer, Inc.*, No. 11 C 5490 (Gender Solutions LPS Flex).

dismiss" directed at the Master Complaint, which is merely an administrative device that Plaintiffs objected to filing in the first place. The court addresses each of these arguments in turn.

A motion under Rule 12(b)(6) for failure to state a claim upon which relief may be granted "must be made before pleading if a responsive pleading is allowed." FED. R. CIV. P. 12(b). A motion for judgment on the pleadings under Rule 12(c) may be filed after pleadings are closed, however, and such a motion is governed by the same standard as a 12(b)(6) motion. *See Buchanan-Moore v. Cnty. of Milwaukee*, 570 F.3d 824, 827 (7th Cir. 2009). Thus, Defendants are free to file a Rule 12(c) motion arguing that complaints failed to state a claim upon which relief can be granted. *See* FED. R. CIV. P. 12(h)(2)(B). The fact that Defendants have styled their motion to dismiss as a Rule 12(b)(6) motion does not alter this analysis. *See Alioto v. Town of Lisbon*, 651 F.3d 715, 718 (7th Cir. 2011) (citing *McMillian v. Collection Prof'ls Inc.*, 455 F.3d 754, 757 n.1 (7th Cir. 2006)). The court concludes that it makes no difference whether Defendants' motion is a 12(b)(6) motion in response to the Master Complaint—which, as an amended complaint, supercedes the original complaint, rendering all prior pleadings without legal effect, *see Massey v. Helman*, 196 F.3d 727, 735 (7th Cir. 1999)—or a motion filed after the close of pleadings under Rule 12(c).

Plaintiffs' second challenge to the propriety of this motion requires more analysis. They contend that a "master motion to dismiss" targeted at the Master Complaint is inappropriate in light of the purposes of a consolidated complaint in an MDL. Plaintiffs cite a number of MDL opinions which recognize that a "master" or "consolidated" complaint is a "procedural device used to promote judicial efficiency and economy," not to be "given the same effect as an ordinary complaint" or considered to "'merge the suits into a single cause, or change the rights of the parties, or make those who are parties in one suit parties in another.'" *In re Propulsid Prods. Liab. Litig.*, 208 F.R.D. 133, 141-42, 144 (E.D. La. 2002) (quoting 9 Charles A. Wright & Arthur R. Miller, *Federal Practice and Procedure* § 2382 (1971)) (citing Diana E. Murphy, *Unified and Consolidated Complaints in Multidistrict Litigation*, 132 F.R.D. 597 (1991)); *see also In re Vioxx Prods. Liab. Litig.*, 239 F.R.D.

450, 454 (E.D. La. 2006) ("[A] master complaint is only an administrative device used to aid efficiency and economy and, thus, should not be given the status of an ordinary complaint."); *In re Digitek Prods. Liab. Litig.*, MDL No. 2:08-md-01968, 2009 WL 2433468, at *8 (S.D. W. Va. Aug. 3, 2009) (considering a motion to dismiss in light of "[t]he administrative nature of a master complaint and its focus on facilitating management of the litigation, as opposed to being a primary operative pleading"). This court agrees that "master" or "consolidated" complaints must be interpreted in light of the "primary purpose" of multidistrict litigation: "to promote efficiency through the coordination of discovery." *In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL No. 1014, 1997 WL 109595, at *2 (E.D. Pa. Mar. 7, 1997); *see also* 28 U.S.C. § 1407(a) ("[T]ransfers for such proceedings will be for the convenience of parties and witnesses and will promote the just and efficient conduct of such actions.").

In light of a master complaint's administrative purpose, several MDL courts have refused to entertain motions to dismiss master complaints where doing so would require case-specific rulings to determine the sufficiency of each individual plaintiff's factual allegations. *See In re Nuvaring Prods. Liab. Litig.*, No. 4:08MD1946 RWS, 2009 WL 4825170, at *2 (E.D. Mo. Dec. 11, 2009); *In re Trasylol Prods. Liab. Litig.*, No. 08-MD-1928, 2009 WL 577726, at *8 (S.D. Fla. Mar. 5, 2009). In *Trasylol*, for example, the court, faced with over 400 separate cases, assessed the sufficiency of the master complaint's fraud claims with "substantial leniency"; the court concluded that any master complaint that contained all of the plaintiff-specific allegations defendant demanded would "completely remov[e] the compromise and attempt at efficiency the Parties and [the court] had in mind in allowing the filing of the Consolidated Master Complaint." *Trasylol*, 2009 WL 577726 at *8. Similarly, the *Nuvaring* court concluded that case-specific rulings on the sufficiency of the plaintiffs' allegations

> "are neither the purpose, nor the forte of a court presiding over a multi-district litigation. A MDL seeks to promote judicial economy and litigant efficiency by allowing the transferee court to preside over matters common among all

> cases. . . . Given this function, the transferee court typically does not rule on cumbersome, case specific legal issues."

Nuvaring, 2009 WL 4825170, at *2 (quoting *In re Phenypropanolamine Prods. Liab. Litig.*, No. MDL 1407, 2004 WL 2034587, at *2 (W.D. Wash. Sept. 3, 2004)). The court agrees with this rationale. With more than 549 individual actions already consolidated in this litigation, the Master Complaint cannot be expected to include specific factual matter for claims that require plaintiff-specific proof. The proper court to hear dispositive motions concerning the sufficiency of plaintiff-specific allegations is the transferor court, *see* Manual for Complex Litigation (Fourth) § 22.37 ("When the MDL pretrial proceedings are concluded and individual cases are remanded to the transferor courts, the transferor judge must decide whether additional discovery and other pretrial work require completion, including deciding dispositive motions), or this court when it considers exemplar cases.

Where defendants bring a motion to dismiss that raises issues common to all plaintiffs, however, the administrative nature of a Master Complaint does not necessarily preclude 12(b)(6) motion practice. Defendants cite a number of cases where MDL courts have entertained motions to dismiss "master" or "consolidated" complaints under such circumstances. *See Ironworkers Local Union 68 v. AstraZeneca Pharm., LP*, 634 F.3d 1352, 1360 (11th Cir. 2011) (affirming dismissal of consolidated RICO and consumer protection claims brought by insurers against drug manufacturer involving an illegal off-label marketing campaign); *In re Katrina Canal Breaches Litig.*, 309 F. App'x 836, 839 (5th Cir. 2009) (affirming judgment on the pleadings dismissing a consolidated complaint brought by property owners against the port commissioners who, by statute, were not responsible for the design, construction, or maintenance of levees and floodgates); *In re FEMA Trailer Formaldehyde Prods. Liab. Litig.*, No. MDL 07-1873, 2008 WL 5217594, at *1-2, 20 (E.D. La. Dec. 12, 2008) (granting in part and denying in part motions to dismiss a master complaint involving breach-of-warranty claims for heightened formaldehyde levels in FEMA-supplied trailers); *In re ConAgra Peanut Butter Prods. Liab. Litig.*, No. 1:07-MD-1845-TWT, 2008 WL 2132233, at *1 (N.D.

Ga. May 21, 2008) (granting in part and denying in part a consolidated complaint arising from peanut butter contaminated with salmonella); *In re Bextra & Celebrex Mktg., Sales Practices & Prod. Liab. Litig.*, No. MDL 05-01699 CRB, 2007 WL 2028408, at *9 (N.D. Cal. July 10, 2007) (sustaining in part and dismissing in part a consolidated complaint brought by consumers against a drug manufacturer alleging a misleading marketing campaign); *In re Bridgestone/Firestone Inc., Tires Prods. Liab. Litig.*, 153 F. Supp. 2d 935, 938-48 (S.D. Ind. 2001) (granting a motion to dismiss state-law claims seeking recall of automobile tires as preempted by federal law). Plaintiffs do not attempt to distinguish these cases. Consequently, the court will consider Defendants' motion to dismiss to the limited extent that it challenges the sufficiency of the factual allegations common to all Plaintiffs.

II. Choice of Law

In its Order concerning Defendants' contacts with prospective expert witnesses who are also treating physicians of individual Plaintiffs, this court agreed with Defendants that the filing of a consolidated, master complaint does not, absent consent of the parties, alter the choice of which state's substantive law governs the claims that originated in transferor courts outside of Illinois. In an attempt to avoid the need to analyze the sufficiency of the Master Complaint under the laws of multiple jurisdictions, Defendants purport to bring this motion against only those cases transferred from Illinois federal courts.[6] For such cases, Defendants urge, the law of either Illinois (where the injury presumptively occurred), or Indiana (the location of Zimmer's headquarters and presumably

[6] For the same reasons that this court will not entertain motions to dismiss the Master Complaint for failure to plead plaintiff-specific facts, the court is skeptical that addressing a motion to dismiss the Master Complaint for such a limited subset of the cases consolidated in this action is an efficient use of the court's time and resources. Were Defendants' motion to turn on peculiar features of Illinois or Indiana law, the court is hesitant to invite further motion practice on the sufficiency of Plaintiffs' Master Complaint under the laws of every other jurisdiction. Because Defendants' motion primarily challenges the sufficiency of the factual allegations under federal pleadings standards, however, and because the court ultimately concludes that Plaintiffs' factual allegations are sufficient, the court will consider Defendants' motion, limited as it is to cases from transferor courts located in Illinois.

where the devices were designed and manufactured), provide the rule of decision. Zimmer's briefs primarily focus on Illinois law, however, with only passing reference to Indiana law in footnotes.

Without making a choice-of-law determination for those cases consolidated from transferor courts located in Illinois, the court will consider the sufficiency of Plaintiff's pleadings under Illinois law.[7] As for issues of federal law, this court applies the law of the Seventh Circuit. *See In re Sears, Roebuck & Co.*, Nos. MDL-1703, 05 C 4742, 05 C 4743, 2006 WL 1517779, at *2 n.1 (N.D. Ill. May 24, 2006) (citing *In re Gen. Am. Life Ins. Co. Sales Practices Litig.*, 391 F.3d 907, 911 (8th Cir. 2004)) ("As a general rule, when a transferee court such as this court receives a case from the MDL Panel, the transferee court applies the law of the circuit in which it is located to issues of federal law.").

III. Pleading Standard

Under Federal Rule of Civil Procedure 8(a)(2), a plaintiff need only provide "'a short and plain statement of the claim showing that the pleader is entitled to relief,' in order to 'give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.'" *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (alteration in original) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)); *see also Erickson v. Pardus*, 551 U.S. 89, 93 (2009). Accordingly, under Rule 8's general notice-pleading regime, a plaintiff need not provide detailed factual allegations. *Twombly*, 550 U.S. at 555; *see also Erickson*, 551 U.S. 89 at 93 ("Specific facts are not necessary . . . ."). When evaluating the sufficiency of a complaint, the court reads its allegations in the way most favorable to plaintiff, accepting well-pleaded allegations as true and drawing inferences in favor of the plaintiff. *AnchorBank, FSB v. Hofer*, 649 F.3d 610, 614 (7th Cir. 2011). Nothing in the Supreme

[7] Defendants contend that the relevant substantive law does not differ between Illinois and Indiana, and therefore no choice-of-law determination is required. Whether or not Defendants are correct about the relevant differences between Illinois and Indiana law, the court takes Defendants' argument to be an admission, for the purposes of this motion, that sufficiency of the Master Complaint under Rule 8 to plausibly state Illinois causes of action will also satisfy the pleading requirements for Indiana causes of action.

Court's recent pleadings jurisprudence casts doubt on these general principles. *See Swanson v. Citibank, N.A.*, 614 F.3d 400, 404 (7th Cir. 2010) ("Critically, in none of the three recent decisions—*Twombly*, *Erickson*, or *Iqbal*—did the Court cast any doubt on the validity of Rule 8 of the Federal Rules of Civil Procedure."); *Brooks v. Ross*, 578 F.3d 574, 581 (7th Cir. 2009) ("Any doubt that *Twombly* had repudiated the general notice-pleading regime of Rule 8 was put to rest two weeks later, when the Court issued *Erickson* . . . .").

The Court has made clear, however, that the "threadbare recitals of a cause of action's elements, supported by mere conclusory statements," are not entitled to the assumption of truth afforded a plaintiff's well-pleaded factual content. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *see also Twombly*, 550 U.S. at 555 ("[A] plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do . . . ." (first alteration in original) (quoting *Papsan v. Allain*, 478 U.S. 265, 286 (1986)). "While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations." *Iqbal*, 556 U.S. at 679. Assuming their veracity, the court must determine whether plaintiff's well-pleaded factual allegations "plausibly give rise to an entitlement to relief." *Id.*

Although "[s]pecific facts are not necessary," *Erickson*, 551 U.S. at 93, the "[f]actual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all of the complaint's allegations are true (even if doubtful in fact)." *Twombly*, 550 U.S. at 555 (citations omitted). Put another way, the complaint must present sufficient factual material to allege a claim that is "plausible on its face." *Id.* at 570. Such facial plausibility exists "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. The reasonable inference must appear to flow from a plaintiff's allegations; if the allegations instead are "'merely consistent with' a defendant's liability," they do not satisfy the plausibility test. *Id.* (quoting *Twombly*, 550 U.S. at 557).

This plausibility analysis is a "context-specific task," and it calls on the court to rely on its experience and to exercise common sense. *Id.*

The Supreme Court has been careful, however, to note that the "plausibility" requirement "does not impose a probability requirement at the pleading stage; it simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence" supporting the plaintiff's legal claims. *Twombly*, 550 U.S. at 556; *see also Iqbal*, 556 U.S. at 678 ("The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that defendant has acted unlawfully."). As the Seventh Circuit reads these decisions,

> "[p]lausibility" in this context does not imply that the district court should decide whose version to believe, or which version is more likely than not. . . . For cases governed only by Rule 8, it is not necessary to stack up inferences side by side and allow the case to go forward only if the plaintiff's inferences seem more compelling than the opposing inferences.

Swanson, 614 F.3d at 404. Rather, the Seventh Circuit understands the Court to require a plaintiff to "give enough details about the subject-matter of the case to present a story that holds together." *Id.*

The Seventh Circuit has also suggested that the "required level of factual specificity rises with the complexity of the claim." *McCauley v. City of Chicago*, 671 F.3d 611, 616-17 (7th Cir. 2011); *see also Swanson*, 614 F.3d at 405 ("A more complex case . . . will require more detail, both to give the opposing party notice of what the case is all about and to show how, in the plaintiff's mind at least, the dots should be connected."). This sliding scale of specificity aligns with the principal policy reason driving the Court's concern about pleading standards: in complex cases, the costs of discovery are high and "often asymmetric, . . . and one way to rein them in would be to make it more difficult to earn the right to engage in discovery." *Swanson*, 614 F.3d at 405; *see also Twombly*, 550 U.S. at 557-58 ("[S]omething beyond . . . mere possibility . . . must be alleged, lest a plaintiff with 'a largely groundless claim' be allowed to 'take up the time of a number of other

people, with the right to do so representing an *in terrorem* increment of the settlement value.'" (quoting *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 347 (2005)) (internal quotation marks omitted)).

II. Sufficiency of Pleadings

A. Design Defect

Defendants concede that Plaintiffs have sufficiently pleaded design defect claims for the MIS tibial components, which was the subject of a Class II recall. Defendants nevertheless contend that the Plaintiffs' factual allegations do not give rise to a reasonable inference that the failure of Plaintiffs' knees was the result of a design defect in the Flex femoral components. Specifically, Defendants argue that while the peer-reviewed journal articles and other sources cited by Plaintiff that report higher revisions rates for recipients of Flex femoral components may be *consistent* with a theory of design defect, they are not enough to support a reasonable inference that the failures were *caused by* defects in the design. Defendants would have this court weigh the probability that the failure of Plaintiffs' knees was the result of a defect in the design of the Flex femoral components against the probability that the failure was due to other factors, such as physician error or Plaintiffs' more active lifestyles. According to Defendants, a reasonable inference of design defect arises only if the Plaintiffs' factual allegations suggest that a design defect was more likely than any of the alternative explanations Defendants raise as affirmative defenses.

The court believes that the Defendants' approach to the "plausibility" analysis is the very type of probability requirement that the Supreme Court cautioned against in *Iqbal* and *Twombly*. The Seventh Circuit has expressly cautioned that *Twombly* does not require a district court to "stack up inferences side by side and allow the case to go forward only if the plaintiff's inferences seem more compelling than the opposing inferences." *Swanson*, 614 F.3d at 404. It is not the role of this court at the pleading stage to prejudge the case by determining whether the affirmative defenses seem more plausible than Plaintiffs' products liability theory. The proper question is whether a reasonable inference can bridge the gap between Plaintiffs' factual allegations and the legal

conclusions they wish to draw, and whether discovery is likely to produce evidence that will further support that inference.

This case is certainly a complex one, both in terms of the size of this MDL and the technical nature of the products involved. That said, the court does not believe the gap between the well-pleaded facts and the legal conclusion for which Plaintiffs argue is as large as in cases where the Supreme Court has found a plaintiff's pleading deficient. In the complex antitrust claims involved in *Twombly*, the Court concluded that evidence of parallel conduct amongst the "baby Bells," without more, did not support a reasonable inference that the companies had illegally conspired to avoid competing with one another. *Twombly*, 550 U.S. at 554. Likewise, in the relatively more straightforward discrimination case presented in *Iqbal, see Swanson*, 614 F.3d at 408 (Posner, J., dissenting) (describing *Iqbal* as "not especially complex"), the Court perceived a large gulf between the alleged mistreatment at the hands of government agents and the conclusion that officials at the highest levels of government were aware of and condoned that treatment for reasons related to the plaintiff's religion, race, or national origin. *Iqbal*, 556 U.S. at 680-83. In contrast, the gap between well-pleaded factual allegations that the Flex femoral components failed at a higher rate than non-Flex components and the conclusion that the failure is attributable to the difference in design between the two components is not so large that Plaintiffs need plead substantial additional facts to make that inference a reasonable one.

Further, the well-pleaded facts in this case make it distinguishable from cases cited by Defendants that courts have dismissed for failure to state a design defect claim. In *Frey v. Novartis Pharmaceuticals Corp.*, a plaintiff who experienced multi-organ hypersensitivity after ingesting anti-seizure medication brought a suit against the drug's manufacturer when the manufacturer later issued a label change and a warning letter to doctors adding a precaution regarding that condition as a potential side effect of the drug. 642 F. Supp. 2d 787, 789-90 (S.D. Ohio 2009). While the case was allowed to proceed on a failure-to-warn theory, the court concluded that with regard to

design defect, the plaintiff had "simply provided a formulaic recitation of the elements of a claim under the statute," and had "not alleged any facts that would permit the Court to conclude that there was a defect in the design or formulation of [the drug] and that the defect was the proximate cause of [the plaintiff's] alleged injuries." *Id.* at 795; *see also Tillman v. Taro Pharm. Indus. Ltd.*, No. 10-cv-04202, 2011 WL 3704762, at *4 (N.D. Ill. Aug. 17, 2011) (concluding that the plaintiff's complaint included "only formulaic recitations of the elements of her cause of action").

In contrast, Plaintiffs allege that the revision rate for Flex knees is higher than for their non-Flex counterparts, and that the Flex knees do not provide a statistically significant advantage in patients' postoperative range of motion—the purported benefit of the Flex knees. Plaintiffs reference studies in peer-reviewed journals that support both of these points. That these studies note their own limitations and the possibility that other causes may explain the higher revision rates does not mean that design defect is not one of the plausible explanations.

Defendants also cite a products liability case from the Eastern District of California for the proposition that "[a] sufficient factual allegation would explain how the particular design of the [product] caused [plaintiff] harm." *Altman v. HO Sports Co.*, No. 1:09-cv-1000 AWI SMS, 2009 WL 4163512, at *8 (E.D. Cal. Nov. 23, 2009); *see also Goodson v. Boston Scientific Corp.*, No. 1:11-CV-3023-TWT, 2011 WL 6840593, at *4 (N.D. Ga. Dec. 29, 2011) (dismissing a design defect claim because "[t]he Complaint does not describe *how* the . . . devices were defective"). In a post-*Twombly/Iqbal* decision, however, the Seventh Circuit rejected a defendant's objection to a products liability claim brought against the manufacturer of a hip replacement system on the grounds that the complaint did not "specify the precise defect." *Bausch v. Stryker Corp.*, 630 F.3d 546, 560 (7th Cir. 2010). The court recognized that "although the complaint would be stronger with such detail," failure to plead such detail did not support dismissal for failure to satisfy Rule 8 pleading requirements. *Id.*

At any rate, the court believes that Plaintiffs here have provided sufficient factual allegations concerning the nature of the defect. In the Master Complaint and in the technical report and presentation, Plaintiff cited to studies that posit that the loosening may be the result of the distribution of the load during deep flexion. Plaintiffs further cite studies that question whether the Flex devices offered a clear advantage in a patient's postoperative range of motion. These allegations give Defendants sufficient notice of the nature of the defect Plaintiffs allege. In the light most favorable to Plaintiff, these factual allegations are sufficient to support a reasonable inference that the product failed to perform as an ordinary consumer would expect and that the benefits of the design do not outweigh the inherent risk of loosening. *See Blue v. Envtl. Eng'g, Inc.*, 215 Ill. 2d 78, 91-92, 828 N.E.2d 1128, 1138-39 (2005) (explaining Illinois's adoption of the consumer-expectation test and the risk-utility test).

B. Failure to Warn

Similar to their argument that Plaintiffs have not pleaded facts sufficient to support the inference that Plaintiffs' injuries were caused by defects in the femoral component, Defendants assert that the Master Complaint does not contain sufficient factual allegations to support a strict liability claim based on a failure-to-warn theory. Specifically, Defendants claim that the Master Complaint lacks factual allegations concerning which product labeling or information contained inadequate warnings; what those warnings should have been; whether Zimmer knew or should have known about the unwarned dangers; and how Zimmer's failure to warn proximately caused Plaintiffs' injuries, which, under the "learned intermediary" doctrine adopted by Illinois law, requires a showing that had Defendants adequately warned Plaintiffs' *physicians*, those physicians would not have chosen to implant the Flex femoral components. *See Hansen v. Baxter Healthcare Corp.*, 198 Ill. 2d 420, 430, 764 N.E.2d 35, 42 (2002).

Upon review of Plaintiffs' factual allegations, the court concludes that they do support a reasonable inference in favor of Plaintiffs' failure to warn claim. Plaintiffs offer detailed factual

allegations concerning Zimmer's marketing of the Flex components: They allege that Zimmer promoted the Flex knees as safe and effective to accommodate up to 155 degrees of flexion, especially in active individuals who perform high-flexion activities such as gardening and kneeling for prayer that require deep flexion. (Master Compl. ¶¶ 102-110; Pls.' Resp. 27-29.) Plaintiffs allege, further, that Zimmer promoted the knees as safe and effective for all patients, even for those who do not have the need of higher flexion. (*Id.* ¶ 69.) Regardless of whether the precise representations Plaintiffs cite were directed to patients or physicians, physicians appear to have received the message: for example, the peer-reviewed studies cited by Plaintiffs, written by physicians who are presumably experts in the field, note that the NexGen components were designed to safely provide high degrees of flexion. *See* Cho et al., *supra*, at 902 ("The NexGen® LPS-flex total knee system was designed to provide 150° of flexion following TKA."); Han et al., *supra*, at 1457 ("The NexGen legacy posterior stabilised (LPS)-flex fixed TKR . . . is designed to allow 155° of knee flexion safely.").

If, as is plausible from Plaintiffs' factual allegations, the deep flexion that the design was meant to accommodate causes loosening in the long run, Zimmer's alleged representations would be misleading without further warnings. As for allegations that Zimmer knew or should have known of the higher risks of loosening, the court notes that even under the heightened pleading standards for fraud, a person's mental state may be alleged generally. *See Burks v. Raemisch*, 555 F.3d 592, 594 (7th Cir. 2009). It is at least plausible that Zimmer was put on notice of the increased risk from the studies and reports of higher loosening rates Plaintiffs cite. Further, with respect to the issue of whether a Plaintiff's physician would have opted against using the Flex femoral components in the face of adequate warning, the type of detail Defendant seeks appears to be plaintiff-specific. For purposes of the Master Complaint, the court concludes Plaintiffs have sufficiently alleged that "proper warning would have been heeded and no health care professional, including Plaintiffs[']physicians, would have used" the Flex femoral components. (Master Compl. ¶¶ 262, 273, 284,

295); *see also Erickson v. Baxter Healthcare, Inc*., 151 F. Supp. 2d 952, 970 (N.D. Ill. 2001) (observing that even at the summary judgment state, "the plaintiffs are entitled . . . to a presumption that a learned intermediary would have heeded the warning given"). Defendants' motion to dismiss the failure to warn claims in Plaintiffs' Master Complaint is denied.

C. Manufacturing Defect

Defendants also contend that Plaintiffs' factual allegations are insufficient to support a plausible claim of manufacturing defect. Similar to their argument concerning design defect, Defendants assert that the Master Complaint merely offers a "formulaic recitation" of the elements of a manufacturing defect, without providing factual allegations concerning the manufacturing specifications and standards and how the product deviated from those specifications and standards. Unlike the challenges to the design defect and failure-to-warn claims, however, Defendants contest Plaintiffs' manufacturing defect claim for both the femoral and tibial components.

As opposed to design defects, where a "specific unit conforms to the intended design but the intended design itself, or its sale without adequate instructions or warnings, renders the product unreasonably dangerous," a manufacturing defect generally "occurs in only a small percentage of units in a product line." *Blue*, 215 Ill. 2d at 89, 828 N.E.2d at 1137. The sheer number of Plaintiffs in this litigation suggests defects in the design of the components, but individual Plaintiffs may have claims for manufacturer defect as well. Consequently, the type of factual allegations Defendants assert are absent from the Master Complaint appear to be plaintiff-specific allegations, the sufficiency of which is best left for a court considering individual plaintiffs' substantive pleadings.

Moreover, as mentioned above, the Seventh Circuit rejected a similar argument that a plaintiff had failed to specify the precise defect that caused her hip replacement to fail. *See Bausch*, 630 F.3d at 560 ("Rule 9(b) does not impose any special requirement that such a claim be pled with particularity, as it does for fraud claims, for example."). Additionally, the Seventh Circuit

noted that it is common for "injured plaintiffs to plead both defective manufacture and defective design and to pursue discovery on both theories." *Id.* The court reasoned that "the victim of a genuinely defective product . . . may not be able to determine without discovery and further investigation whether the problem is a design problem or a manufacturing problem." *Id.* Consequently, the most appropriate time to address whether these cases involve design defect claims or manufacturing defect claims is at summary judgment. *See id.* (collecting cases).

D. Remaining Claims

The court need address Defendants' remaining objections to the Master Complaint only briefly. Defendants' motion to dismiss the parallel negligence claims and claims for implied warranty of merchantability concerning the Flex femoral components rest on the argument, already rejected by the court, that Plaintiffs have not offered adequate factual allegations for the court to draw a reasonable inference that the Flex femoral components were defective. The remainder of Defendants' motion seeks dismissal of claims against both the Flex femoral and MIS tibial components for failure to plead plaintiff-specific facts.

The perceived inadequacy of the Master Complaint's factual allegations supporting the negligent misrepresentation, express warranty, and implied warranty of fitness claims concern the absence of plaintiff-specific facts. For instance, Defendants assert that "[n]owhere does the Master Complaint identify a single statement from the array of promotional material, package inserts, and surgical technique instructions related to the Devices . . . that was communicated to any *particular* Plaintiff or physician and that constitutes an actionable misrepresentation or warranty." (Zimmer's Mot. to Dismiss, In Part, Master Long Form Compl. and Jury Demand, at 27) (emphasis added). Likewise, Defendants also seek to dismiss Plaintiffs' consumer fraud claims under the Illinois Consumer Fraud Act ("ICFA"), 815 ILCS 505/1 *et seq*, for failure to include plaintiff-specific facts about particular misrepresentations. Unlike Plaintiffs' other claims, however, the ICFA claim is a species of fraud claim subject to the heightened pleading standard of Rule 9. *See Greenberger v.*

GEICO Gen. Ins. Co., 631 F.3d 392, 399 (7th Cir. 2011). Consequently, to properly plead an ICFA claim, "a plaintiff must state the identify of the person making the misrepresentation, the time, place, and content of the misrepresentation, and the method by which the misrepresentation was communicated." *ABN AMRO, Inc. v. Capital Int'l Ltd.*, 595 F. Supp. 2d 805, 849 (N.D. Ill. 2008).

In the *Trasylol* case mentioned above, the court addressed the pleading of fraud in an MDL master complaint. *See Trasylol*, 2009 WL 577726, at *8-9. The court concluded that particularized pleadings were not feasible in a master complaint, and instead preferred to "assess the sufficiency of plaintiffs' claims with substantial leniency, especially when the information that may or may not support Plaintiffs' claims is largely within the control of the Defendants." *Id.* at *8. The court cautioned, however, that "leniency must not overreach so as to effect a negation of the policy behind Rule 9." *Id.* at *9. While the court concluded that the plaintiffs had "minimally stated enough to allow discovery" into what the defendant knew of the safety of the drug in question, the court noted that information concerning misrepresentations lay "largely in the possession of Plaintiffs' physicians, and so, any allegation of fraud based on such statements must be pled with particularity in the individual Plaintiff's complaint, and be subject to discovery during the case-specific discovery state if, and only if, properly alleged." *Id.*

Like the *Trasylol* court, this court cannot envision a Master Complaint pleaded with the type of plaintiff-specific particularity Defendants believe is necessary. A motion to dismiss the Master Complaint is not the appropriate time to address deficiencies in plaintiff-specific allegations in the Short Form complaints or the Plaintiffs' fact sheets. For purposes of the Master Complaint, the court concludes that the factual allegations concerning the marketing and promotion of the devices are sufficient to put Defendants on notice of the types of representations Plaintiffs believe form the basis of these claims. The court considers summary judgment upon a more fully developed record the most appropriate time to address these claims. Should any Plaintiff assert reliance on a fraudulent statement made directly to them or their physician by Zimmer agents or other persons,

however, the court expects the factual allegations in Plaintiffs' fact sheets to satisfy Rule 9's particularity requirement. *See Trasylol*, 2009 WL 577726, at *12.

Finally, Defendants ask this court to dismiss Plaintiffs' claim for punitive damages. Defendants contend that Plaintiffs have not pleaded sufficient facts to make a plausible claim that Defendants acted "'with fraud, actual malice, deliberate violence or oppression, or . . . willfully, or with such gross negligence as to indicate a wanton disregard for the rights of others.'" *Slovinski v. Elliot*, 237 Ill. 2d 51, 58, 927 N.E.2d 1221, 1225 (2010) (quoting *Kelsay v. Motorola, Inc.*, 74 Ill. 2d 172, 186, 384 N.E.2d 353, 359 (1978)). Because Plaintiffs' consumer fraud claim remains, and because Plaintiffs contend that Defendants alleged misrepresentations were not only negligent, but reckless, the court concludes that dismissal would be premature.

CONCLUSION

For the above reasons, Defendants' Motion to Dismiss, in Part, Master Long Form Complaint and Jury Demand [258] is denied.

ENTER:

Dated: August 16, 2012

REBECCA R. PALLMEYER
United States District Judge